

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)
BETWEEN
GENENTECH, INC
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080
AND
THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING
GENENTECH UMBRELLA AGREEMENT
MODIFICATION NO. 0005
Date: March 27, 2020

Agreement No.: HHSO100201800036C

Total Amount of the Agreement: (b)(4)

Total Estimated Government Funding of the Agreement: (b)(4)

Total Estimated Recipient Funding of the Agreement: (b)(4)

Funds Obligated: (b)(4)

Period of Performance:

CLIN	Title	Start	End
(b)(4)			

Authority: 10 USC 2371 and Sections 319(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417, 319L(c)(5) of the Public Health Service Act, 42 USC 247d-7e(c)(5).

Line of Accounting and Appropriation:

CLIN	Title	Requisition (OS)	CAN	Object Class	Amount (Gov't Share)	Changed / Execution Status
(b)(4)						

(b)(4)

PURPOSE: The purpose of this modification is to accomplish the following:

(b)(4)

- 2.) Modify the SOW to extend the period of performance for CLIN 0005.

This Agreement is entered into between the United States of America, hereinafter called the "Government", represented by the Department of Health and Human Services (HHS) and Genentech, Inc., hereinafter called "Recipient", pursuant to and under U.S. Federal law. Recipient and the Government are each referred to as a "Party" and collectively referred to as the "Parties".

Signatures	
For GENENTECH, INC.	FOR THE UNITED STATES OF AMERICA ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA), DIVISION OF CONTRACT MANAGEMENT AND ACQUISITIONS
(b)(5)	<p>George J. Keane Jr -S Digitally signed by George J. Keane Jr -S Date: 2020.03.27 19:35:30 -04'00'</p> <p>George J. Keane, Jr., Other Transactions Agreement Officer, ASPR/BARDA/DCMA Date:</p>
Date: March 27, 2020	

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ARTICLE VI: COST SHARING

ARTICLE VI: COST SHARING, is modified to revise and replace the entire Article VI with the following:

- A. The terms of this Article VI apply to the cost sharing for (b)(4) and (b)(4). (b)(4) This framework may be applied by mutual agreement to any of the Options or to any modification to the effort required under the (b)(4) and (b)(4). The Parties acknowledge that the exercise of Options will be subject to the availability of funding.
- B. Recipient estimates that the cost of completing the (b)(4) (b)(4). This amount reflects Recipient's estimate and may overstate or understate the actual cost of completing the (b)(4). (b)(4) The Recipient agrees to fund approximately (b)(4)

1. TOTAL PROJECT COST SUMMARY FOR BASE PERIODS AND OPTION PERIODS

(b)(4)

2. COST SHARE FOR BASE PERIOD AND OPTION PERIODS – RECIPIENT

(b)(4)

3. COST SHARE FOR BASE PERIOD AND OPTION PERIODS – U.S. Government

(b)(4)

4. PROJECTED FUNDING PROFILE

(b)(6)

(b)(6)

(b)(6)

(b)(6)

D. Recipient will provide a Financial Status Report to the Government, which will, among other things, identify the total actual costs of performing this Agreement. This report is for informational purposes only. Recipient's accounting for Government-reimbursed and Recipient costs shall be in accordance with the Recipient's accounting practices but must comply with International Financial Reporting Standards (IFRS). (b)(4)

(b)(4) (b)(4) Recipient must comply with the cost principles set forth in Article VII for Government reimbursed costs.

E. For purposes of the Financial Status Report, Recipient shall (b)(4)

(b)(4)

F. Recipient's entitlement to reimbursement for approved costs under this Agreement is not contingent upon Recipient's cost share equaling any specific ratio or percentage of total costs. The Parties' remedy to address the total cost exceeding or falling below the estimated total cost to perform the SOW is to agree to a mutual modification of the Agreement or a termination of the Agreement.

ARTICLE VII: SPECIAL CLAUSES

The following text is appended to Article VII: SPECIAL CLAUSES

R. Any product (b)(4) in the United States under this Agreement will be

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(b)(6)



ATTACHMENT 1: STATEMENT OF WORK (Revised)

ATTACHMENT 1: STATEMENT OF WORK, is modified to revise and replace ATTACHMENT 1 with the following:

Dated: March 27, 2020

Recipient: Genentech, Inc.

ATTACHMENT 1. Statement of Work

Independently, and not as an agent of the Government, the Contractor (Genentech) shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

(b)(4)

(b)(9)

Contractor will create a framework for Contractor and BARDA to collaborate through their Alliance Management team. Contractor will develop a schedule for meetings that are designed to ensure collaboration between BARDA and Contractor on areas of mutual interest and progress towards the project objectives. Contractor will manage day-to-day communication and reporting to BARDA for funded projects.

1.1.1. Integrated Product Development Plan

Period of Performance: September 27, 2018 to September 30, 2023

Description of Work: Contractor will compile all necessary materials and finalize all aspects of the project related to preparing the Integrated Product Development Plan (IPDP). This will include finalizing critical path milestones, Work Breakdown Structure (WBS), Risk Mitigation Plan, and Integrated Master Schedule (IMS). The final deliverable of the IPDP will represent the finalization and approval of all project elements between Contractor and BARDA. The IPDP, including any Deviation Reports, will be updated as necessary during the course of the project.

WBS#	Milestone	Deliverable
(b)(4)		

1.1.2. Contract Management

Period of Performance: September 27, 2018 to September 30, 2023

Description of Work: Contractor will comply with all reporting requirements as outlined in the BAA and requested by BARDA. Reporting will include at a minimum monthly technical progress reports and a final report. Additional deliverables such as deviation reports, technology packages, experimental protocols, publications, press releases, security reports, or other reports may be provided based on requests from BARDA. Contractor and BARDA will engage in regular meetings to coordinate and review project activities. Meetings will be both face-to-face and teleconference/video conference. The first official meeting will be the face-to-face kickoff meeting, followed by status update meetings on a regular basis, ad hoc teleconferences and site visits, and annual meetings to report on the period of performance activities.

WBS#	Milestone	Deliverable
1.1.2.2	Reporting	All required reports as listed in the BAA and requested by BARDA
1.1.2.2.1	Monthly Technical Progress Reports	A report detailing the prior month's technical progress and activities planned for the following month. Report will be delivered prior to the 15th of the month following the reporting period.
1.1.2.2.2	Final Report	The Final Progress Report will include a complete summary of all work performed during the entire contract period of performance. A Draft Final Progress Report will be delivered 45 days prior to contract expiration for BARDA review and comments. A Final Progress Report will be delivered at contract expiration.
1.1.2.3	Meetings	Meeting presentation materials as needed for all teleconference and/or in-person meetings.
1.1.2.3.1	Kickoff Meeting with BARDA	Contractor will prepare all necessary presentation materials for the kickoff meeting.

1.1.3. (b)(4)

Period of Performance: September 27, 2018 to September 30, 2023

(b)(4)

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Period of Performance: September 27, 2018 to September 30, 2021

bx1

WBS#

Milestone

Deliverable

Period of Performance: July 1, 2021 to September 30, 2021

bx1

Period of Performance: June 30, 2021 to February 28, 2022

bx1

WBS#

Milestone

Deliverable

1

Period of Performance: September 27, 2020 to September 30, 2023

WBS#

Milestone

Deliverable

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Period of Performance: **March 27, 2020 to September 30, 2021**

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0.04

Period of Performance: March 27, 2020 to September 30, 2021

Period of Performance: March 27, 2020 to September 30, 2021

WBS#

Milestone

Deliverable

0.04

Period of Performance: March 27, 2020 to September 30, 2021

WBS#

Milestone

Deliverable

0.04

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Period of Performance: March 27, 2020 to September 30, 2021

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WBS#

Milestone

Deliverable

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Period of Performance: March 27, 2020 to September 30, 2021

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WBS#

Milestone

Deliverable

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WBS#

Milestone

Deliverable

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CLIN	TYPE	WP	WBS	Title	Objectives

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Period of Performance: September 27, 2018 to September 30, 2023

WBS# Milestone

Deliverable

Period of Performance: September 27, 2018 to September 30, 2023

the face-to-face kickoff meeting, followed by status update meetings on a regular basis, ad hoc teleconferences and site visits, and annual meetings to report on the period of performance activities.

WBS#	Milestone	Deliverable
	Reporting	All required reports as listed in the BAA and requested by BARDA
	Monthly Technical Progress Reports	A report detailing the prior month's technical progress and activities planned for the following month. Report will be delivered prior to the 15th of the month following the reporting period.
	Final Report	The Final Progress Report will include a complete summary of all work performed during the entire contract period of performance. A Draft Final Progress Report will be delivered 45 days prior to contract expiration for BARDA review and comments. A Final Progress Report will be delivered at contract expiration.
	Meetings	Meeting presentation materials as needed for all teleconference and/or in-person meetings.
	Kickoff Meeting with BARDA	Contractor will prepare all necessary presentation materials for the kickoff meeting.

Period of Performance: September 27, 2018 to September 30, 2023

Period of Performance: September 27, 2018 to March 31, 2021

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WBS#

Milestone

Deliverable

Period of Performance: September 27, 2018 to March 31, 2021

WBS#

Milestone

Deliverable

Period of Performance: September 27, 2018 to March 31, 2021

WBS#

Milestone

Deliverable

Period of Performance: September 27, 2018 to March 31, 2021

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Period of Performance: September 27, 2018 to March 31, 2021

WBS#

Milestone

Deliverable

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Period of Performance: **June 5, 2019 to December 31, 2021.**

Schedule: June 5, 2019 to December 31, 2021

WBS#	Task	Schedule	Milestone	Deliverable

WBS#	Task	Schedule	Milestone	Deliverable

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WBS#	Task	Schedule	Milestone	Deliverable
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WBS#	Task	Schedule	Milestone	Deliverable

Schedule: April 1, 2020 to December 31, 2021

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(b)(4)

Schedule: January 30, 2020 to September 30, 2020

(b)(4)

Schedule: January 30, 2020 to December 31, 2021

(b)(4)

WBS#	Task	Schedule	Milestone	Deliverable
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(b)(4)

Schedule: January 30, 2020 to December 31, 2021

(b)(4)

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WBS#	Task	Schedule	Milestone	Deliverable
(b)(4)				

Schedule: January 30, 2020 to December 31, 2021

(b)(4)

WBS#	Task	Schedule	Milestone	Deliverable
(b)(4)				

7.3. Project Management

Schedule: June 1, 2021 to December 31, 2021

(b)(4)

WBS#	Task	Schedule	Milestone	Deliverable
(b)(4)				

-----End of Statement of Work-----

ATTACHMENT 2. REPORTING REQUIREMENTS

ATTACHMENT 2: REPORTING REQUIREMENTS, is modified by appending the following table to section D. Deliverables.

1. Delivery of the following items shall only be required for (b)(4)

#	Type of Deliverable	Frequency/ Time Periods	Description of Deliverable	Reporting Procedures	Quantity/ Forms
1.	Daily project status update	Daily, except for weekends and Federal holidays, or as agreed by the two parties	<p>Upon request of the Government, the Recipient shall provide by email a daily update to BARDA project staff.</p> <p>The updates will address study progress including enrolment and site status, and other significant updates.</p> <p>Updates may be shared with senior Government leaders (b)(4)</p> <p>unless the update includes confidential information in which case Recipient shall provide the update in both confidential and non-confidential formats.</p> <p>Upon request of the Government, updates may also occur on weekends and on federal holidays, provided at least 24 hours' notice.</p>	<p>Update will be provided to OTTR by email.</p> <p>Upon request of the Government, Recipient may participate in teleconferences, as mutually agreed.</p> <p>No agenda or meeting minutes will be required.</p>	1 Electronic Copy by Email to OTTR
2	Product Development	Within one month of	The Recipient shall submit a detailed	Recipient will submit Product Development	1 Electronic Copy to OTTR

#	Type of Deliverable	Frequency/ Time Periods	Description of Deliverable	Reporting Procedures	Quantity/ Forms
	Source Material and Manufacturing Report	contract award and with substantive changes	spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites.	Source Material Report within one month of contract award, within 30 days of substantive changes made to sources and/or materials, or on the 6th month anniversary of the work package being approved (OT modification). The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days of receipt. Recipient will address, in writing, any concerns raised by BARDA. The Recipient is not required to change its methods or processes based on BARDA's concerns and/or recommendations.	and OTAS by Email; Upload to eRoom.
3	Recipient Locations	Within 5 business days of contract award and substantive changes	The Recipient shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include vendors.	Within 5 business days of contract award. Within 5 business days after a substantive location or capabilities change.	1 Electronic Copy to OTTR and OTAS by Email; Upload to eRoom.